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STATE PASS TO OMB/OIRA FOR DUDLEY AND MANCINI, USTR FOR SANFORD

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SUBJECT: TRANSATLANTIC REGULATORY DIALOGUE ADDRESSES REGULATORY QUALITY, TRADE, INVESTMENT AND IMPORT SAFETY

¶1. Summary: At the 25 April High Level Regulatory Cooperation Forum (HLRCF), senior U.S. and EU regulators discussed strengthening EU-US cooperation on import product safety, enhancing information sharing, collaborating on risk analysis, and the final joint OMB/Secretariat General report on the impact of domestic regulation on international trade and investment. A subsequent session with non-government stakeholders addressed public consultation in the EU and the U.S. regulatory process. U.S. and EU chairs discussed the HLRCF results at the 13 May TEC meeting. End Summary.

History of HLRCF

¶2. The High-level Regulatory Cooperation Forum (HLRCF) was set up at the April 2005 US-EU Summit to allow regulators to discuss cross-cutting topics of general interest and issues that may be the responsibility of multiple regulatory authorities. As such, it provides a platform for exchanges between regulators and stakeholders on priorities in reducing unnecessary regulatory differences and thereby advancing transatlantic economic integration.
¶3. The first dialogue in January 2006 focused on "good regulatory practices." Hosted by the European Commission, nearly 150 people attended the conference, including senior EU and U.S. regulators, representatives of the EU Member States, members of the European Parliament and the U.S. Congress, and a large number other stakeholders, including the Trans-Atlantic Business and Consumer Dialogues (QTABDQ and QTACDQ). The primary purpose of the first dialogue was to glean insights into Qhow we regulateQ on both sides of the Atlantic. A large part of the discussion was devoted to general regulatory policy, comparing the EU and U.S. regulatory systems and approaches in assessing the impact of regulations.

¶4. The second HLRCF, hosted by U.S. Department of Health and Human Services (HHS) Deputy Secretary Alex M. Azar II on 3 May 2006, sought to move forward on a common agenda of promoting better-quality regulation, minimizing regulatory divergences, increasing consumer confidence, and

facilitating Trans-Atlantic commerce. Participation was of similar caliber and quality as the first Forum. Azar addressed the HLRCF on the importance of collaboration between the U.S. Government and the EC as they develop regulations. He also shared insights on the strengths of the U.S. rule-making process, highlighting our transparency and stakeholder involvement our use of the most contemporary and robust science and our commitment to cost-justification and judicial review.

¶5. The third Forum, hosted by the Office of Management and Budget (OMB) on 7 November 2007, had a public and non-public portion, focusing on import safety and coordination on understanding risks before considering development of regulation. The non-public portion provided an excellent opportunity to cross-fertilize ideas and address incorrect presumptions of the others' regulatory system, facilitating intensification of regulatory cooperation and information sharing. The public portion discussed a draft OMB/Secretariat General joint report reviewing how the EU and U.S. analyze the impacts of regulations on international trade and investment.

April 25 HLRCF Meeting

¶6. At the fourth HLRCF on April 25 in Brussels, senior regulators discussed strengthening EU-US cooperation on import product safety, enhancing

information sharing, collaboration on risk analysis, and the final joint OMB/Secretariat General report on the impact of domestic regulation on international trade and investment. Susan Dudley, Administrator for OMBQs Office of Information and Regulatory Affairs (OIRA), co-chaired the HLRCF and led the Washington-based delegation that included OMB/OIRA, FDA, CPSC, OSHA and CBP; and USEU representatives from USTR, CBP, USDOC and State. European Commission Director General for Enterprise and Industry (DG ENT) Heinz Zourek co-chaired, joined by regulators from the Public Health and Consumer Affairs (SANCO) Directorate, Customs and Taxation Directorate (TAXUD), DG ENT and the Secretariat General.

Import Safety

¶7. The report on our respective approaches to import safety in key areas (cars, toys, electrical equipment for consumer use, pharmaceuticals, cosmetics, food, and customs issues related to these products), and cooperation in these areas, was nearly complete by the time of the HLRCF; however, recommendations on next steps were still being finalized. The discussion at the HLRCF focused on proposed recommendations for improved information sharing. For the most part, both sides came to agreement on these recommendations. The discussion also focused on more general challenges to improved information sharing.

¶8. Confidentiality, especially with respect to sharing product recall and other business confidential information with the member states, surfaced as a key problem. While discussing OSHAQs suggested recommendation in the draft report that OSHA may benefit from access to the EUQs RAPEX system (their rapid alert system for dangerous non-food products), the Deputy Director General of DG SANCO Paola Testori-Coggi demanded "reciprocity" before sharing information that they would consider

helpful to us. OSHA's Ed Foulke explained that his agency did not regulate products per se, but their impact on workers in the workplace. Deputy Commissioner of FDA Randall Lutter pointed out how we readily shared a new testing methodology to detect a contaminant in heparin that could and did save lives. This information was immediately shared in order to contain the negative public health effects. OIRA Administrator Susan Dudley pointed out that our goal should be sharing information as expeditiously as possible to protect our citizens.

¶9. European Medicines Agency (EMEA), DG Enterprise and FDA have a confidentiality agreement; however, the Commission does not have full competence for regulation of pharmaceuticals, and must defer to member states in particular instances. FDA has regulatory authority and responsibility for enforcing its laws, including with respect to information sharing. The difficulty FDA has is that EMEA must share information it receives from FDA with the member states, which have no obligation to keep the information private. To fill this gap, EMEA is negotiating a network of confidentiality agreements with its EU member state regulator counterparts, which would oblige the member state regulators to keep FDA information confidential. DG Zourek stated that although pharmaceuticals are somewhat unique due to the sharing of responsibility with member states, the Commission may be able to apply this strategy to other product classes, and that in particular this may be a model that could help, for example, CPSC and SANCO to intensify information sharing once CPSC receives legislative authority to do so. (Comment: Statutory limitations were discussed at the May 13 TEC as well but leaders also recognized that such barriers could

be overcome with the political will to share vital safety information such as in the case of heparin. End comment.)

¶10. Both sides recognized the importance of closer cooperation and coordination in dealing with China, the key source of consumer product imports for both the US and the EU. CPSC and SANCO will jointly reach out to China in September and Commissioner Kuneva will be hosting a trilateral product safety conference (EU, U.S., China) in November 2008.

¶11. Testori-Coggi also expressed concern with certain elements of the FDAQs Food Protection Plan, i.e. proposals for inspection fees for imports, systematic registration with the FDA, etc. She said that if the FDA would decide to implement the plan, the EC would want to achieve recognition that EU food is as safe as U.S. food.

¶12. Assistant Secretary for Occupational Safety and Health Ed Foulke suggested the EU and U.S. also exchange information on their approach to the safety of nanotechnology. Zourek invited Foulke to take a look at and comment on the CommissionQs nanotech Staff Working Paper, which Zourek said would be released mid-May. (Comment: This communication was scheduled to be released since last September, but many believe it has been delayed due to differences of opinion on how the Commission should handle regulation of nanotechnology applications. The College of Commissioners recently debated the form of the document, apparently choosing to release as a Staff Working Paper as opposed to a Communication, which now allows more flexibility to change opinions in the future. See reftel BRUSSELS 184)

Risk Analysis

¶13. OIRA Administrator Dudley characterized an underlying goal of our risk analysis dialogue as not necessarily to converge on the same policies, since we operate in different systems, but rather to see if we can agree on the underlying risks for which both the EU and U.S. are considering regulation. FDA mentioned an idea for reviewing analysis of a potential endocrine disruptor to facilitate illustration of methodological differences, but there were different thoughts on the usefulness of defining specific case studies. Many agreed that a discussion of case studies might be ripe for the fall 2008 HLRCF. Zourek expected a report to come from this meeting that could be delivered to the 3rd TEC.

¶14. In part in preparation for that, OIRA and SecGen/SANCO and other regulatory agencies from the US, EU and Canada will hold a government-only workshop on risk assessment July 10-11, and then SANCO will host a major international conference in Brussels later this year, possibly November 13-14.

Joint Report on Incorporating Trade and Investment Impacts in Regulatory Analyses
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¶15. OIRA and SecGen had virtually completed their report on how our impact assessments account for impacts on trade and investment, including responding to, and in some cases incorporating, stakeholder comments at the time of the Forum. When discussing opportunities for public comment, Dudley and others mentioned that U.S. regulatory agencies must consider all comments received equally, i.e. comments from EU companies are just as valid as those from U.S. companies. The Administrative Procedure Act requires US regulatory agencies to provide reasoned responses to all inquiries, although some statutes constrain the factors that

may be considered (e.g., the Clean Air ActQs focus is on U.S. air quality). OMB and SecGen agreed at the Forum to report steps they take to more fully account for trade and investment impacts. The report was delivered to the TEC on May 13.

¶16. They also agreed that "case studies" on impact assessments would be useful to better understand how our respective guidelines can and should be applied, and how our analysis might differ on reviewing alternative approaches to effectively achieve policy priorities. Although the initiative was not yet fully defined, suggestions included two distinct projects. One study would focus on legislation/regulation for which the U.S. and the EU have already done an impact assessment in the past, an ex-post assessment. Both sides would apply the otherQs guidelines to the impact assessment and see whether methodologies are different.

¶17. Another study would deal with an area where one side is considering regulating and the other already has regulated (and done an impact assessment). These case studies would include a review of how trade and investment would be affected by the various options; however, the case studies would focus on the application of all aspects of our respective guidelines. Forum participants identified two possibilities: biofuels sustainability (the EU has done impact assessments on portions of their proposals and we are soon to

begin ours), (and electronic stability control for cars (we have done ours and are using it as a case study with the Canadians and Mexicans, the Commission should be presenting theirs by 20 May).

Future Agenda Items Q Standards?

¶18. In terms of future agenda items, DG Zourek suggested focusing on how using (varying) standards affects technological innovation and competitiveness. Zourek clarified standards to be those as defined under TBT, thus voluntary. He suggested we could "revive the US-EU standards dialogue" with the Commerce Department and discuss these issues in 2009. Dudley suggested that one recommendation coming from their joint report was to look at international standards first, and determine if there was a necessity to go beyond them. A previously planned U.S.-EU standards DVC took place on Monday April 28.

¶19. Comment: The government to government part of this HLRCF was marred to some extent by having each side sit opposite the other, as opposed to interspersed with each other, as had been done in the previous one. This arrangement encouraged more of a Qtrade negotiationQ atmosphere. End comment.)

Public Session with Stakeholders

¶20. The public session was separated into two parts. First, Susan Dudley, Heinz Zourek, and Alexander Italianer summarized the morning meetings between U.S. and EC officials on import safety, risk analysis, and impact assessment, stating that the Forum would deliver both the import safety information sharing report and the final Joint Report on Incorporating Trade and Investment Impacts in Regulatory Analyses to the May 13 TEC. (On the margins of this meeting, Jim Murray, on behalf of the TACD, suggested it would be very useful to receive either an early copy of these reports, or a summary, before the TEC meetings. The USG agreed to provide a summary of the reports to the Advisors, but not to the general public, before the TEC.)

¶21. Second, the public session addressed the role

of public consultation and notice and comment in our respective systems. Susan Dudley and Alexander Italianer presented an overview of the U.S. and EC regulatory development processes, with a particular emphasis on the role of public participation. Then the session continued with a panel consisting of business, consumer, and government representatives from both sides of the Atlantic.

¶22. Highlights of the many issues discussed included:

--A suggestion that full consultation procedures should be used for the ECQs QcomitologyQ process. (Note: Comitology refers to the process by which the Community adopts implementing measures pursuant to existing legislation. In general, the Commission makes a proposal which is then considered by a committee of experts from the member states before adoption, either by the Council or by the Commission. The European Parliament has just forced the Commission and Council to amend this comitology process to allow the Parliament to veto comitology decisions if these are determined to either exceed or amend the legislative language.)

--A suggestion that any consultation requirements on either side be viewed by regulators as minimum requirements. Transparency should not be viewed as a burden, but rather as an essential part of the process of developing quality policies.

--A suggestion that transparency is getting better. There appears to be more momentum to these latest U.S.-EU cooperative efforts.

--A suggestion that a simple principle that all submissions to the EC eventually be published would be a welcome improvement in transparency.

--A comment that the REACH consultation may have been hurt by what was characterized by the DG ENT panelist as businesses exaggerating the impact of REACH.

-- Referring to the EUQs demand for use of suppliers declaration of conformity for low-voltage electrical products, TACDQs Jim Murray commented that OSHAQs Nationally Recognized Testing Laboratories (NRTL) system must be compared to the EUQs suppliers declaration of conformity (SDOC) combined with post-market surveillance, and that it is not clear which one is more effective or burdensome.

--Ed Foulke mentioned that the previous RFI on the subject did not yield much support for SDOC, but signaled fairly strongly in response to a question that OSHA would develop a new RFI on the issue.

--Regarding the use of committees in the US, FDA (Randall Lutter) summarized the six separate statutes (not just FACA) FDA had to comply with.

--Jim Murray of TACD suggested the transatlantic economic framework concentrate not only on reducing trade barriers, but on taking joint action on common problems such as climate change and obesity. He also suggested the U.S. and the EU develop an overall strategy on nanotechnology, QOtherwise, we will end up with a system we now have for GMOs. Nobody is happy with it, unless maybe when you are a believer in chaos theory.

¶23. Audience questions and comments to the panel:

--Reinhard Quick of the German Chemicals Industry (VCI) suggested the EU and the U.S. coordinate their implementation of the GHS on labeling and classification of chemicals. He commented that REACH had actually widened the transatlantic

regulatory divide.

--The European cosmetics industry focused on the fast-approaching deadline for non-animal tests for cosmetics products, seeing that as a priority both sides needed to address to avoid trade disruptions.

--Another commenter asked if there were any mechanisms to QforceQ international stakeholder concerns to be taken into account. Several panel members responded that stakeholders must continue to be active participants in the public comment and consultation process. In the U.S. system at least, the U.S. representatives suggested that neither domestic or foreign firms, nor other interested parties, are forced to participate. If they do participate, however, a U.S. agency has an obligation to respond to their concerns.

¶24. Comment: The public session was long on speakers and short on interactive dynamics. By the time the long list of speakers had completed their thoughts, there was little time to discuss some of the very thoughtful comments made to the U.S. and the EU on public consultation, notice and comment, and how to improve the regulatory process. End comment.

Murray